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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,122	01/14/2002	Vijay K. Iyer	98-503-WO	9429

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04/01/2004

EXAMINER

KREMER, MATTHEW J

ART UNIT	PAPER NUMBER
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3736

19

DATE MAILED: 04/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/581,122

Applicant(s)

IYER ET AL.

Examiner

Matthew J Kremer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-11,13 and 14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,13 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claim 1 is objected to because of the following informalities. Claim 1 recites the limitation "the light generating means" in line 12-13, which should actually be "the first light source" and/or "the second light source". Appropriate correction is required.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 9-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,529,064 to Rall et al. (cited by Applicant) in view of U.S. Patent 5,782,756 to Mannheimer (Mannheimer ('756)). Rall et al. teaches light generating means 12 which are placed at two different locations which result in two different optical measurement paths, light detecting means 13, and a measuring unit 3. (Figs. 1 and 4 of Rall et al.). Rall et al. does not teach the particulars of the light source or the measuring unit. Mannheimer ('756) teaches a light source and measuring unit used for monitoring oxygen saturation in a fetus, which would fulfill the requirements of providing a light source and a measuring unit as set forth in Rall et al. Therefore, it

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would have been obvious to one having ordinary skill in the art at the time the invention was made to use the light source and measuring unit of Mannheimer ('756) in the device and method of Rall et al. since Rall et al. requires the use of light sources and a measurement unit and Mannheimer ('756) teaches a suitable light source and measurement unit. In regard to claim 9 and 11, Mannheimer ('756) teaches a measuring unit 34 that controls the light sources, measures the incident light, and produces a measurement. The measurement comprises measurements common to both optical paths since both emitter locations have the same wavelengths. In regard to claims 9-10 and 13-14, the measuring unit produces a measurement $\text{SpO}_2^{\text{corrected}}$ from selectively weighted ratios of the light measured from the three wavelengths along each of the plurality of optical paths. According to equation 4 of Mannheimer ('756), the 735/900 ratio is weighted $(k+1)$ while the 660/900 ratio is weighted $-k$.

4. Claims 1 and 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,218,962 to Mannheimer et al. (Mannheimer ('962)) in view of U.S. Patent 5,782,756 to Mannheimer (Mannheimer ('756)). Mannheimer ('962) teaches a first light source to provide light along a first optical path 262, a second light source to provide a light along a second optical path 254, a first light detector 266, a second light detector 258 (Fig. 9 of Mannheimer ('962)), and a processing unit 110 (Fig. 3 of Mannheimer ('962)). The processing unit of 110 receives the output of the light detectors (Fig. 2 of Mannheimer ('962)) and produces measurements indicative of the oxygen saturation of the subject. The measurement includes a first measurement

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common to the first and second optical paths (the 660 nm light) that is distributed independently in each optical path because of the various biological structures that the light encounters in the tissue. Each optical path also has a different measurement associated with each optical measurement path (the 900 nm light). Mannheimer ('962) does not teach that the processing unit includes controls for the light sources.

Mannheimer ('962) teaches the use of LEDs (column 4, lines 4-28 of Mannheimer ('962)). It is well known that the LED drive is placed in the pulse oximeter as a means of operating the LEDs. (Fig. 5 of Mannheimer ('756)). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the LED driver of Mannheimer ('756) in the pulse oximeter of Mannheimer ('962) since Mannheimer ('962) teaches the use of LEDs and Mannheimer ('756) teaches a means of operating the LEDs. In regard to claim 3, two wavelengths, 660 and 900 nm, are used. (column 4, lines 4-28 of Mannheimer ('962)).

In regard to claims 4-5, Mannheimer ('962) does not teach the use of three wavelengths for each probe and a unit for processing the three wavelengths.

Mannheimer ('756) teaches that the use of three wavelengths that will compensate for variations caused by differences in the scattering of the radiation at different wavelengths. (column 4, lines 24-35 of Mannheimer ('756)). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the three wavelengths and processing unit of Mannheimer ('756) in the method and device of Mannheimer ('962) since the use of three wavelengths will compensate for variations caused by differences in the scattering of the radiation at different

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wavelengths. In summary, the combination teaches two light sources with each light source emitting three wavelengths; a first light detector that detects the three wavelengths from one light source; and a second light detector that detects the three wavelengths from the other light source. (Fig. 9 of Mannheimer ('962)). The processing unit calculates a first saturation oxygen measurement from one light source-light detector pair using the processing formulas taught by Mannheimer ('756); a second saturation oxygen measurement from the other light source-light detector pair using the processing formulas taught by Mannheimer ('756); using both saturation oxygen measurements to calculate the difference (reference numeral 142 of Fig. 3 of Mannheimer ('962)), calculating the comparison (reference number 143 of Fig. 3 of Mannheimer ('962)), and calculating the final oxygen saturation (reference numeral 146 of Fig. 3 of Mannheimer ('962)). When the light is measured, each optical path has a measurement in common (the 660 nm light) that is distributed independently in each optical path because of the various biological structures that the light encounters in the tissue. Each optical path also has a different measurement associated with each optical measurement path (the 900 nm light). It can even be said that each optical path also has a third measurement (the 735 nm light) but that is not required by the claims of the present application.

In regard to claim 6, the light source-detector pairs can be on a single or dual probe. (Figs. 8-9 of Mannheimer ('962)).

5. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,218,962 to Mannheimer et al. (Mannheimer ('962)) in view of U.S. Patent 5,782,756 to Mannheimer (Mannheimer ('756)) as applied to claim 1, and further in view of U.S. Patent 5,551,424 to Morrison et al. The combination does not teach a light transmitting fiber. The combination teaches the use of LEDs. Morrison et al. teaches that LEDs can be substituted with light transmitting fibers. (Abstract of Morrison et al.). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the light transmitting fiber for the LEDs of the combination since Morrison teaches that LEDs can be substituted with light transmitting fibers.

6. Claim 7 is rejected under 35 U.S.C. 103(a) as being obvious over U.S. Patent 5,218,962 to Mannheimer et al. (Mannheimer ('962)) in view of U.S. Patent 5,782,756 to Mannheimer (Mannheimer ('756)) as applied to claim 6, and further in view of U.S. Patent 6,298,253 to Buschmann

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed

in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

The combination does not teach the use of a spiral needle comprising a plurality of window areas suitable for light emission and light detection. The combination teaches that other emitter/detector configurations are possible. (column 6, lines 11-22 of Mannheimer ('962)). Buschmann teaches the placement of emitter and detectors on a spiral needle. (Fig. 5b of Buschmann). Such a configuration falls within the scope of other emitter/detector configurations as set forth in the combination. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to place an emitter/detector pair on a spiral needle as disclosed by Buschmann since Mannheimer ('962) teaches other detector configurations are possible and Buschmann teaches one such configuration.

Response to Arguments

7. In regard to the rejections of claims 9-11 and 13-14 in view of the Rall-Mannheimer combination, Applicant's arguments filed 1/8/2004 have been fully considered but they are not persuasive. In regard to claim 9, the combination teaches a light generating means (Fig. 4 of Mannheimer ('756)), a light detecting means 13 (Fig. 2 of Rall), and a processing system 34 that controls the light generating means, receives the signal from the light detecting means, and produces a measurement corresponding to a weighted combination of the wavelengths (Fig. 5 of Mannheimer ('756)). The measuring unit produces a measurement $\text{SpO}_2^{\text{corrected}}$ from selectively weighted ratios of the light measured from the three wavelengths along each of the plurality of optical paths. According to equation 4 of Mannheimer ('756), the 735/900 ratio is weighted $(k+1)$ while the 660/900 ratio is weighted $-k$. The Applicant contends that that Mannheimer ('756) does not teach using three wavelengths. The Examiner respectfully disagrees. As stated in the Abstract of Mannheimer ('756), the "present invention utilizes at least three wavelengths of electromagnetic radiation for determining a blood constituent, such as arterial oxygen saturation." Numerous references to the use of three wavelengths are cited in Mannheimer ('756) such as Box A of Fig. 6; column 4, lines 24-43; Equation 4 in column 7; and claim 1. Indeed, one of the principal aspects of the Mannheimer ('756) disclosure is directed to the use of three wavelengths. Therefore, the Examiner is slightly confused how the Applicant can assert that Mannheimer ('756) does not teach the use of three wavelengths. In regard to claim 10, Equation 4 of Mannheimer ('756) teaches that there are at least two sets of wavelengths

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of light from the three wavelengths: (1) 735 and 900 nm and (2) 660 and 900 nm. (Equation 4 in column 7 of Mannheimer ('756)). In regard to claims 11 and 14, the combination teaches light sources (Fig. 4 of Mannheimer ('756)) in two different locations for generating light (Fig. 4 of Rall) that are detected by a signal light detector 13 (Fig. 4 of Rall). Since there are two different light sources in different locations, the light beams generated by the sources are transmitted along different optical measurement paths. When the light is measured, each optical path has a measurement in common (the 660 nm light) that is distributed independently in each optical path because of the various biological structures that the light encounters in the tissue. Each optical path also has a different measurement associated with each optical measurement path (the 900 nm light). It can even be said that each optical path also has a third measurement (the 735 nm light) but that is not required by the claims of the present application. The signals are processed to determine oxygen saturation. (Abstract of Mannheimer ('756)). In regard to claim 13, the measuring unit produces a measurement $SpO_2^{corrected}$ from selectively weighted ratios of the light measured from the three wavelengths along each of the plurality of optical paths. According to equation 4 of Mannheimer ('756), the 735/900 ratio is weighted $(k+1)$ while the 660/900 ratio is weighted $-k$.

8. Applicant's arguments with respect to claims 1 and 3-8 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 703-605-0421. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mary Beth Jones can be reached on 703-308-3400. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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